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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,632	04/06/2000	Goro Hori	506.35379CC2	9269

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/544,632

Applicant(s)

Hori

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 11, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 18, and 28-43 is/are pending in the application.
- 4a) Of the above, claim(s) 17 and 28-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 35-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8 6) ☐ Other:

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DETAILED ACTION

The request for the extension of time, amendment and supplemental declaration filed on 3-11-02 are acknowledged.

- 1. Newly submitted claims 17 and 28-34 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally presented claims were drawn to a composition and a method of improving the cholesterol metabolism whereas the newly added claims 17 and 28-34 are drawn to the treatment of various diseases which include obesity, diabetes and even myocardial infarction; the methods are different.**

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 17 and 28-34 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims included in the prosecution are 18 and 35-43.

Claim Rejections - 35 U.S.C. § 112

- 2. The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. **Claims 18 and 35-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific proteins listed in the specification and the cholesterol lowering effect of the complex, does not reasonably provide enablement for generic 'plant protein'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.**

It is common knowledge that there numerous proteins present in both animals and plants and instant specification is not adequately enabling to the broad term. Broad claims must have broad basis of support in the specification; in the absence of such support, claims must be limited to specific protein-phospholipid complexes.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant cite Fig. 1 in Journal of Food Science and argue that one of ordinary skill in the art would have used not only wheat protein or soybean protein, but plant proteins in general. This argument is not found to be persuasive since as already pointed out above, there is no broad support in the specification for generic 'plant proteins' and just because soybean protein acts in certain way, proteins from other sources would have the same function. To cite specific examples, the protein 'hemoglobin' performs the function of carrying oxygen whereas the protein, albumin does not. Enzymes which are

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proteins do not perform the same functions of hemoglobin and albumin. The rejection is maintained.

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 18 and 35-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugano (J. Nutr., 1990) or Sugano (Atherosclerosis, 1988) by themselves or in combination with Williams (Perspectives in Biology and Medicine, 1984).

As pointed out above, these references teach the effectiveness of soybean protein-phospholipid complexes in lowering the cholesterol levels (note the abstracts and Tables in both). The amounts of phospholipids in Sugano however, are lower than the amounts in instant invention.

Williams teaches the effectiveness of phospholipids in cholesterol removal (note the entire article).

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It would have been obvious to alter the amounts of the phospholipids in the phospholipid-soy protein complex in Sugano, with the expectation of obtaining the best possible results, since Williams teaches that phospholipids by themselves lower the cholesterol. The criticality of the hydrolysis of the protein after forming the complex is not readily apparent to the examiner. In the absence of a showing the criticality, hydrolysis of the protein before or after is deemed to be a manipulatable parameter to obtain the best possible results.

6. Claims 18 and 35-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirtori (Ann. Nutr. Metab. 1985) in combination with Williams (Perspectives in Biology and Medicine, 1984).

Sirtori teaches the effectiveness of lecithinated soy proteins in lowering cholesterol (note the abstract). The amount of lecithin in the complex however, is lower than the amount in instant invention.

Williams teaches the effectiveness of phospholipids in cholesterol removal (note the entire article).

It would have been obvious to alter the amounts of the phospholipids in the lecithinated soy proteins in Sirtori with the expectation of obtaining the best possible results since Williams teaches that phospholipids by themselves lower the cholesterol.

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Applicant's arguments have been fully considered, but are not found to be persuasive. Although these arguments pertain to the original rejections, the examiner will address them. Applicant, based on the declaration, argues that the combination produces a synergistic effect. These arguments based on the declaration are not found to be persuasive for the following reasons. First of all, the studies were conducted with phospholipase digested complex and not on undigested product; secondly, there are no values for lecithin itself to determine whether the values are additive or synergistic. With regard to applicant's arguments that in instant invention, the phospholipid is bound, the examiner points out that close examination of applicant's procedure indicates that the two components are simply stirred together; nevertheless, the examiner points out that Sirtori teaches a complex.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

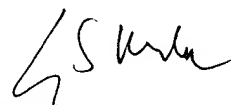
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

May 29, 2002